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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
[illegible]	05/23/01	JAROCH	S SCH 1707

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EXAMINER	
ROBINSON, B	
ART UNIT	**PAPER NUMBER**
1625	7

DATE MAILED: 08/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/787,848	Applicant(s) JAROCH ET AL.	
	Examiner Binta M. Robinson	Art Unit 1625	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *8,10 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Detailed Action

1. The examiner notes the applicant's election of example 2 or the species in claim 5. The election of species will be used as a reference point for the examiner to create a natural genus based on a liberal interpretation of the doctrine of legal and chemical equivalence and restriction will be required under 35 U.S.C. 121 and 372.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7,9 drawn to a compound where R1 and R2 are H, C1-C6 alkyl, R3 is saturated or unsaturated C1-C5 alkylene radical, R4 is as claimed, except when R4 joins with R5 to form a five or six membered carbocyclic compound, R5 and R6 are independently as claimed R7, R18, R19 are independently as claimed , R8, R11, and R12 are a, b, or c, R14 is H, and R15 is phenyl, a process for the production of a compound of formula I, and a method for treating neurodegenerative diseases comprising administering a therapeutic amount of the compound.

Group II, claim (s) 1-7,9 drawn to a compound where the radicals R1, R2, R3, R4, R5, R6, R7, R8, R11, R12, R18, R19, are all other radicals not claimed in group I, a process for the production of a compound of formula I, and a method for treating neurodegenerative diseases comprising administering a therapeutic amount of the

compound.

Group III, claim(s) 8, drawn to a process for the production of a pharmaceutical composition.

Group IV, claim(s) 10, drawn to a process for the production of a compound.

Group V, claim(s) 11, drawn to a compound of formula IIb.

3. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The species in group I, II and group IV lack a common core. Additionally, group I comprises a category of invention pertaining to a product and a process of use of said product. The remaining process of preparation claims, and compound claim each comprise a different category of invention directed to a process for the manufacture of said product and a process of use of the said product. Under ***In re Ochai***, if a compound is found to be allowable, at that time, all of the claims drawn to all methods of making the allowable compound can be rejoined to the case and allowed if there are no other outstanding problems with the claims.

4. Claims 8, 10, and 11 and the unelected portions of claims 1-7 and 9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. By virtue of the applicant's election of species which falls into Group I, group I will be examined. If groups II-V are pursued in divisional applications, they may be subject to further restriction requirements.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while providing enablement for imidazole, indole, isooxazole, isothiazole, furan, oxadiazole, oxazole, pyrazine, pyridazine, pyrimidine, pyridine, pyrazole, pyrrole, tetrazole, thiazole, triazole, thiophene, thiadiazole, benzimidazole, benzofuran, benzoxazole, isoquinoline, and quinoline, piperidine, pyrrolidine, morpholine, thiomorpholine, hexahydroazepine, and piperazine, does not reasonably provide enablement for R14 and R15 coming together with the nitrogen atom to form all 5- to 7-membered saturated heterocycle with can be optionally substituted as claimed in claim 1, page 3, ones 21-24, and does not reasonably provide enablement for R4 and R5 in claim 1, lines 13-14, page 2 and all other occurrences, equal to all five or 6 membered carbocyclic rings, which can be

substituted with NR14R15. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-7, 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, page 2, lines 13-14, and all other occurrences throughout claims 1-7 and 9, the phrase "R4 and R5 together with 2 adjacent carbon atoms form a five-or six-membered carbocyclic compound, which can be substituted with NR14R15", is indefinite. This phrase is so broad as to render the claim meaningless. Which carbocyclic rings is the applicant claiming?

keep but modify

B. In claim 1, page 3, lines 16-18, and all other occurrences throughout claims 1-7 and 9, the phrase "5- or 6-membered heteroaryl with 1-4 nitrogen, oxygen or sulfur atoms, which can be annelated with benzene , whereby the aryl radical and the heteroaryl radical.." is indefinite. The phrase is so broad as to render the claim meaningless. Which heteroaryl rings are the applicants claiming?

C. In claim 1, page 3, line 21-25, page 3, the phrase "R14 and R15 together with the nitrogen atom form a 5- to 7-membered saturated heterocycle, which can contain another oxygen, nitrogen or sulfur atom and can be substituted with C1-4 alkyl or a phenyl, benzyl or benzoyl radical that is optionally substituted with halogen, or an unsaturated 5-membered heterocycle, which can contain 1-3 N atoms and can be substituted" is indefinite. The phrase is so broad as to render the claim meaningless. Which heterocycle rings are the applicants claiming?

keep

D. In claims 6-7, the term "pharmaceutical agent" is indefinite because it is not a statutory class of invention. The phrase "pharmaceutical composition" is suggested.

E. In claim 9, the phrase "neurodegenerative diseases" is indefinite. The phrase is so broad as to encompass a wide range of diseases. Which neurodegenerative diseases is the applicant claiming?

F. In claims 6 and 8, the applicant doesn't use the term "effective amount" of the compound in combination with a pharmaceutical acceptable carrier being administered to a host in need thereof.

8. The IDS filed 6/25/01 has been considered.

9. The WO 99/41240 reference noted on the International Search Report as an X reference does not appear to be an X reference.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Alan L. Rotman

ALAN L. ROTMAN
PRIMARY EXAMINER

BMR
8/26/01